REMARKS

Claims 1, 3-19, 22-24 and 42-59 are pending in the present application. Claims 1, 3-4, 7 and 42 have been amended. Claims 2, 25-41 and 60 have been canceled.

Reconsideration of the claims is respectfully requested.

35 USC §103, Obviousness

The Examiner has rejected claims 1, 3-4, 6-19, 22-24, 42-50 and 52-59 under 35 U.S.C. §103 as being unpatentable over Jonsson (U.S. Patent No. 5,098,372) in view of Abbot (U.S. Patent No. 5,588,816). These rejections are respectfully traversed.

In rejecting the claims, the Examiner writes:

> Jonsson discloses a first pump (10) that is configurable to pump a first metered amount of a first fluid through a first delivery line (11) to a catheter (12); a second (19) pump that is configurable to pump a second metered amount of a second fluid through a second delivery line (Fig 2) separate from said first delivery line, to said catheter, wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a connection point (12) of said first and second delivery lines to said catheter.
> Jonsson does not detail the controller of this device.
> Abbott teaches a processor (46) connected to control first (74) and said second (76) pumps such that said metered amount has a definable relationship to said first metered amount (abstract).

Jonsson teaches an apparatus that withdraws blood from a patient and processes the blood to produce an overall systemic effect on the patient (i.e. anticoagulation). Similarly, Abbott also treats blood outside of the body before introducing the blood back into general circulation, producing a system effect.

In contrast to the references, the present invention provides a means for targeting drug delivery to a specific organ by delivering the therapeutic agent directly into local circulation proximal to the target organ, wherein only the target organ receives the drug. This has the advantage of allowing the effects of the drug to be confined to the target organ while minimizing general systemic effects, particularly when short acting drugs are used. Jonsson and Abbott do not achieve this localized effect since they treat blood outside of the body and return it to general circulation to achieve a systemic effect. The present invention has nothing to do with blood processing.

Furthermore, because the therapeutic agent is not combined with the blood until just before entry into the target organ, the present invention can deliver short acting drugs (e.g., adenosine) that would otherwise break down soon after contacting blood, before reaching the desired organ through general circulation. Again, Jonsson and Abbott cannot overcome this problem because they combine the therapeutic agent (anticoagulant) with the blood outside of the body and then introduce it into circulation. Short acting agents such as adenosine would degrade before even leaving the Jonsson or Abbott devices, let alone before reaching the target organ through general circulation.

In response to the above arguments, the Examiner writes:

> Applicant has argued that the references do not teach targeting an organ to reduce systemic effects. In response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural different between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The Examiner appears to be ignoring the method claims 42-58. The present invention is not limited to just an apparatus. The operational steps recited in claim 42 are not taught or suggested in Jonsson or Abbott, alone or in combination. As explained above, the present invention is not concerned with blood treatment like the prior art references. It provides a method for targeted drug delivery.

Furthermore, the structures of the prior art are not capable of performing the intended use of the apparatus recited in the claims. Neither Jonsson nor Abbott disclose a catheter inserted into a vessel proximate to a target organ as recited in the present claims. Jonsson merely discloses a needle (12) that is used to withdraw and subsequently re-infuse blood from a blood vessel. A needle is not the same as a catheter, and the distinction between the two has been well established in the medical field for decades. They are not functionally synonymous, nor can the functions of the catheter be carried out by the needle disclosed in Jonsson. There is no teaching or suggestion anywhere in Jonsson that needle 12 is anything other than a standard intravenous needle. Therefore, the needle can only introduce fluids into general circulation. Aside from peripheral blood vessels, the disclosed needle cannot be inserted into a vessel proximal to an organ, for example such as the heart (as recited in claim 3), nor can it be inserted into a circulatory

vessel remote from a target organ and maneuvered to the target organ (as recited in claim 24) the way a catheter can.

Nor are the Jonsson and Abbott inventions able to keep blood and medication-containing fluids separate from each other until they enter a catheter at the target organ. If one attempted to perform the targeted drug delivery of the present invention by simply reversing the flow through the Jonsson apparatus, the blood coming from line 11 and the medication coming from container 18 would combine at the needle 12 at the point of intravenous entry and would enter general circulation, not the target organ.

As such, the Jonsson invention, even with the controller disclosed in Abbott, cannot deliver a drug directly to a target organ wherein only the target organ receives medication-containing blood producing a local therapeutic effect on the target organ while minimizing systemic effects.

The Examiner goes on to write:

> For example, using a short acting drug would reduce system effects because the drug is delivered into a circulatory vessel and degrades before it has a chance to produce a system effect.

While this statement is true, it also overlooks the fact that a short acting drug administered as suggested will also have no effect on the target organ either because it degrades so quickly upon entering circulation. This problem goes to the very heart of the present invention. The present invention simultaneously accomplishes the dual purposes of treating the target organ while also minimizing or avoiding systemic effects. The prior art references cannot be used to accomplish these dual functions. Therefore, the Examiner's statement above merely reinforces the distinction between the invention and the prior art.

Because claims 5 and 51 depend from claims 1 and 42, respectively, they are distinguished from Jonsson, Abbot and Gillies for the reasons explained above.

Therefore, it is respectfully asserted that the rejection of claims 1, 3-19, 22-24, 42-59 under 35 USC §103 has been overcome and should be withdrawn.

CONCLUSION

It is respectfully urged that the subject application is patentable over the references cited by Examiner and is now in condition for allowance. Applicants request reconsideration of the application and allowance of the claims.

The Examiner is cordially invited to contact the undersigned attorney at 972.367.2001.

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Respectfully submitted,

By: _____

David W. Carstens
Registration No. 34,134
Attorney for Applicants

CARSTENS & CAHOON, LLP
PO BOX 802334
Dallas, TX 75380
(972) 367-2001 *Telephone*
(972) 367-2002 *Facsimile*